



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

PROSPECTIVE GRANT OF EXCLUSIVE LICENSE: Identification of Non-invasive Biomarkers of Coordinate Metabolic Reprogramming in Colorectal Tumor

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Cary Pharmaceuticals, Inc. (“Cary”) located in Great Falls, VA, USA.

Intellectual Property:

1. United States Provisional Patent No. 61/755,891, issued January 23, 2013, entitled “Identification of Non-invasive Biomarkers of Coordinate Metabolic Reprogramming Colorectal Tumor”;
2. International Patent Application No. PCT/US2014/012758 filed January 23, 2014 entitled “Compositions and Methods for Detecting Neoplasia” [HHS Reference No. E-020-2013/0-PCT-02]

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use will be limited to the use of Licensed Patent Rights for the commercial development of an FDA approved diagnostic/prognostic kit or a class III diagnostic test for human colorectal adenoma (non-malignant polyp) and carcinoma.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K.

Chatterjee, Ph.D., M.B.A., Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; E-mail: chatterjeesa@od.nih.gov.

SUPPLEMENTARY INFORMATION:

The technology identifies a set of non-invasive metabolic biomarkers in urine samples that are mechanistically associated with colorectal carcinogenesis in a mouse model. In addition, pathways related to the production of these metabolites are also found to be dys-regulated in human colorectal cancer tissues. These indicate that changes in

urinary metabolites may be helpful in screening and diagnosis of colorectal cancers. Furthermore, the mechanistic association of these pathways with proliferation suggests that these biomarkers may also be helpful in evaluating and monitoring therapeutic response, remission and relapse in colorectal cancer patients.

This technology is intended for use as an adjunctive screening test for the detection of colorectal tumor or adenoma. A positive result may indicate the presence of colorectal cancer or premalignant colorectal neoplasia (adenoma). This urine based screen would not replace colonoscopy but would assist in the recommendation for additional testing or intervention. Compared to colonoscopy, the currently most commonly used colorectal cancer screening/diagnostic test, the test based on this new technology is no-invasive, cost effective and safer. This technology would be intended for patients who are typical candidates for colorectal cancer screening, adults of either sex, 50 years or older, who are at average risk of developing colorectal cancer.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and,

to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 11, 2014

Richard U. Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

[FR Doc. 2014-19144 Filed 08/12/2014 at 8:45 am; Publication Date: 08/13/2014]